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10/055,675	01/23/2002	Robert N. Hotchkiss	369526-101	7937

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EXAMINER	
PANNALA, SATHYANARAYA R	
ART UNIT	PAPER NUMBER
2164	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,675	HOTCHKISS ET AL.	
	Examiner	Art Unit	
	Sathyanarayan Pannala	2164	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8,11-21,23,25 and 28-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,11-21,23,25 and 28-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Amendment filed on 1/30/2006 has been entered with amended claims 1, 3-4, 8, 11, 18, 20-21, 25, 34-37 and 47-48 and canceled claims 5-7, 22 and 24 in response to the Office Action mailed on 11/1/2005. Claims 1-4, 8, 11-21, 23, 25, 28-55 are pending in this Office Action.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-4, 8, 11-21 23, 25 and 28-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rienhoff, JR. et al. (USPA Pub., US2003/0208454) hereinafter Rienhoff, in view of Fagan et al. (USPA Pub., US2003/0110058) hereinafter Fagan, in view of Bianco et al. (USPA Pub., US2003/0082865) hereinafter Bianco, and in view of Smirniotopoulos et al. (US Patent 7,080,098) hereinafter Smirniotopoulos.

4. As per independent claim 1, Rienhoff teaches by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph [0006]). Rienhoff teaches the claimed "a computer system operable to service user requests and provide users with information responsive to the user requests" as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph [0029]). Further, Rienhoff teaches the claimed "a database coupled to the computer system, wherein the database is operable to store user data and study data" as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028). Phenotypic data may be stored in a database 105 and the server system may invite user to submit

biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Further, Rienhoff teaches the claimed "the study data includes candidate data associated with candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, and at least one dataset associated with at least one of the candidate subjects" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further, Rienhoff and Fagan do not teach explicitly event data. However, Bianco teaches "event data for tracking events associated with medical treatment of candidate subjects" as electronic patient healthcare system 1 and method for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery (Fig.1, page3, 3, paragraph [0078]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Bianco's teachings would have allowed Rienhoff's system to provide an interactive, electronic patient healthcare system to facilitate a full array of education and preparation tools for guiding a patient through a medical event (see Bianco, page 1, paragraph 0010).

Further, Rienhoff teaches the claimed "the computer system is further operable to limit communication of electronic messages between users having a specific role in connection with a specific study" as online event involves users, physicians, researchers and all these have specific role (see page 4, paragraph 0044).

Further, Rienhoff and Bianco do not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed "the dataset is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph 0005).

Finally, Rienhoff, Fagan and Bianco do not teach explicitly role-based access control. However, Smirniotopoulos teaches the claimed, the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user, access to the system for specified roles (Fig. 2, col. 3, lines 32-49). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Smirniotopoulos' teachings would have allowed Rienhoff's system to provide a system that is robust, interactive, and permits geographically remote practitioners to create, update, and relationally search multimedia medical information (see Smirniotopoulos, col. 1, lines 39-42).

5. As per dependent claim 2, Rienhoff teaches the claimed "the event data includes data events that are scheduled (Examiner interpreted as punctual) events and unscheduled events (Examiner interpreted online event as unscheduled event) or both" as online events relating to genetics, various health-related issues, diseases, and medical conditions. Online events could be scheduled interviews on punctual basis (page 4, paragraph [0044]).

6. As per dependent claim 3, Rienhoff teaches the claimed "the computer system is operable to send and receive electronic messages between at least two users" as the information could be directed to individual users via email or web pages viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph 0047).

7. As per dependent claim 4, Rienhoff teaches the claimed "the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study" as online event involves users, physicians, researchers and all these have specific role (see page 4, paragraph 0044).

8. As per dependent claim 8, Rienhoff teaches the claimed "the role defines data access rights granted at a dataset definition level or data item definition level or both" as user may be given strict control in determining who may access information they have

submitted which of the information may be accessed and in what form the information is provided to others (page 4, paragraph 0041).

9. As per dependent claim 11, Rienhoff teaches the claimed "the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a users ability to view privacy data" as the users information may be provided to others in an aggregated form and which does not identify individual user (page 4, paragraph 0041).

10. As per dependent claim 12, Fagan teaches the claimed "the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings (Fig. 9-10, page 3, paragraph 0035).

11. As per dependent claim 13, Fagan teaches the claimed "the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata" as the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables

as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated form the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

12. As per dependent claim 14, Fagan teaches the claimed "a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device" as the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated form the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

13. As per dependent claim 15, Fagan teaches the claimed "a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language" as the data presented to FDA is different form the data presented to Product release and the languages used from on system to another system will be different and large pharmaceutical research firms provide different data access and analysis model (Fig. 1, page 2, paragraph 0020 and 0005).

14. As per dependent claim 16, Fagan teaches the claimed "the database stores an audit record of data access including information relating to the data accessed, user, date and time" as FDA maintains the audit trail and it can be tracked down using the interrelationships 300 (Fig. 14, page 3, paragraph 0039).

15. As per dependent claim 17, Rienhoff teaches the claimed "at least a portion of the user data or study data is stored in the database in an encrypted format" as user may execute the informed consent from electronically via encryption (Fig. 7B, page 9, paragraph 0101).

16. As per independent claim 18, Rienhoff teaches by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.)

from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed step of "storing user data and study data in a database coupled to the computer system" as phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph [0039]). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph [0082]).

Further, Rienhoff teaches the claimed "the study data includes candidate data associated with candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, and at least one dataset" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further, Rienhoff and Fagan do not explicitly teach event data. However, Bianco teaches "event data for tracking events associated with medical treatment of candidate subjects" as electronic patient healthcare system 1 and method for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery (Fig.1, page3, 3, paragraph [0078]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Bianco's teachings would have allowed Rienhoff's system to provide an interactive, electronic patient healthcare system to facilitate a full array of

education and preparation tools for guiding a patient through a medical event (see Bianco, page 1, paragraph 0010).

Further, Rienhoff and Bianco do not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed step of "defining in a computer system at least one dataset using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (page 1, paragraph 0005).

Finally, Rienhoff, Fagan and Bianco do not teach explicitly role-based access control. However, Smirniotopoulos teaches the claimed, the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user, access to the system for specified roles (Fig. 2, col. 3, lines 32-49). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Smirniotopoulos' teachings would have allowed Rienhoff's system to provide a system that is robust, interactive, and permits geographically remote

practitioners to create, update, and relationally search multimedia medical information (see Smirniotopoulos, col. 1, lines 39-42).

17. As per dependent claim 19, Rienhoff teaches the claimed step of "the event data includes data of events that are scheduled (Examiner interpreted as punctual) [see page 4, paragraph 0044] events, unscheduled (Examiner interpreted online as unscheduled) [see page 4, paragraph 0044] events, or both" as online events relating to genetics, various health-related issues, and diseases, medical conditions. Online events could be could be scheduled interviews on punctual basis (page 4, paragraph 0044).

18. As per dependent claim 20, Rienhoff teaches the claimed "the computer system is operable to send and receive electronic messages between at least two users" as the information could be directed to individual users via email or web pages viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph 0047).

19. As per dependent claim 21, Rienhoff teaches the claimed "the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study" as online event involves users, physicians, researchers and all these have specific role (see page 4, paragraph 0044).

20. As per dependent claim 23, Rienhoff teaches the claimed step of "the user data includes at least one role associated with each user" as in step 610 a business concept

is prompted by a web page may describe what will be done with information submitted by users, who will have the access to the information, the revenue sources of operators of the web site, the database, etc (page 7, paragraph 0080).

21. As per dependent claim 25, Rienhoff teaches the claimed step of "the role defines data access rights granted at a dataset definition level, data item definition level or both" as user may be given strict control in determining who may access information they have submitted which of the information may be accessed and in what form the information is provided to others (page 4, paragraph 0041).

22. As per dependent claim 28, Rienhoff teaches the claimed step of "the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a user's capability to view privacy data" as the users information may be provided to others in an aggregated form and which does not identify individual user (page 4, paragraph 0041).

23. As per dependent claim 29, Fagan teaches the claimed step of "the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata

both in terms of variable descriptors as well as measure definitions and groupings (Fig. 9-10, page 3, paragraph 0035).

24. As per dependent claim 30, Fagan teaches the claimed step of "the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata" the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated form the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (see Fagan, Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

25. As per dependent claim 31, Fagan teaches the claimed step of "a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device" as the data displayed using database tables is different as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables as described by the dataset metadata

both in terms of variable descriptors as well as measure definitions and groupings. The two displays will be different because the data presented to FDA is different from Product Release, for example, FDA approval phase 40 provides the additional data and uses the data collected and integrated form the previous phase to perform its analysis, whereas Product release the data relates to how the biomedical product is performing in the field (see Fagan, Fig. 1, 9-10, page 3, paragraph 0035 and page 2, paragraph 0020).

26. As per dependent claim 32, Fagan teaches the claimed step of "a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language" as the data presented to FDA is different form the data presented to Product release and the languages used from on system to another system will be different and large pharmaceutical research firms provide different data access and analysis model (see Fagan, Fig. 1, page 2, paragraph 0020 and 0005).

27. As per dependent claim 33, Fagan teaches the claimed step of "the database stores an audit record of data access including information relating to the data accessed, user, date and time" as FDA maintains the audit trail and it can be tracked down using the interrelationships 300 (Fig. 14, page 3, paragraph 0039).

28. As per independent claim 34, Rienhoff teaches by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed "a computer system operable to service user requests and provide users with information responsive to the user requests" as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph 0029). Further, Rienhoff teaches the claimed "a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies" as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028). Phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082).

Further, Rienhoff teaches the claimed "the study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing

specimens associated with the candidate subjects, and at least one dataset associated with at least one of the candidate subjects" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further, Rienhoff and Fagan do not explicitly teach medical event. However, Bianco teaches "event data for tracking events associated with medical treatment of candidate subjects" as electronic patient healthcare system 1 and method for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery (Fig.1, page3, 3, paragraph [0078]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Bianco's teachings would have allowed Rienhoff's system to provide an interactive, electronic patient healthcare system to facilitate a full array of education and preparation tools for guiding a patient through a medical event (see Bianco, page 1, paragraph 0010).

Further, Rienhoff teaches the claimed "at least one dataset, wherein user data includes at least one role associated with each user" as in step 610 a business concept is prompted by a web page may describe what will be done with information submitted by users, who will have the access to the information, the revenue sources of operators of the web site, the database, etc (page 7, paragraph 0080). Further, Rienhoff teaches the claimed "the role defines data access rights granted at one of a dataset definition level, data item definition level, or both" as developing trust is to provide users with control and privacy rights over information they submit to the web site, and make those rights known to the user (page 4, paragraph 0041).

29. As per independent claim 35, Rienhoff teaches by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed "a computer system operable to service user requests and provide users with information responsive to the user requests" as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph 0029). Further, Rienhoff teaches the claimed "a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies" as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028). Phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph [0039]). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph [0082]).

Further, Rienhoff teaches the claimed "the study data includes candidate data associated with candidate, subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, and at least one dataset associated with at least one of the candidate subjects" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further, Rienhoff and Fagan do not teach explicitly event data. However, Bianco teaches "event data for tracking events associated with medical treatment of candidate subjects" as electronic patient healthcare system 1 and method for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery (Fig.1, page3, 3, paragraph [0078]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Bianco's teachings would have allowed Rienhoff's system to provide an interactive, electronic patient healthcare system to facilitate a full array of education and preparation tools for guiding a patient through a medical event (see Bianco, page 1, paragraph [0010]).

Further, Rienhoff teaches the claimed "user data includes at least one role associated with each user" as in step 610 a business concept is prompted by a web page may describe what will be done with information submitted by users, who will have the access to the information, the revenue sources of operators of the web site, the database, etc (page 7, paragraph 0080). Further, Rienhoff teaches the claimed "the computer system is operable to limit communication of electronic messages between users to those users having a specific role in connection with a specific study" as the

information could be directed to individual users via email or web pages viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph 0047).

Further, Rienhoff and Bianco do not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed "at least one dataset and wherein the dataset is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph 0005).

Finally, Rienhoff, Fagan and Bianco do not teach explicitly role-based access control. However, Smirniotopoulos teaches the claimed, the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user, access to the system for specified roles (Fig. 2, col. 3, lines 32-49). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Smirniotopoulos' teachings would have allowed Rienhoff's system

to provide a system that is robust, interactive, and permits geographically remote practitioners to create, update, and relationally search multimedia medical information (see Smirniotopoulos, col. 1, lines 39-42).

30. As per independent claim 36, Rienhoff teaches by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph [0006]). Rienhoff teaches the claimed "servicing user requests and providing users with information responsive to the user requests" as the user computer 108 and the internet 106 may request of server system 102 health related information and in response, the server system 102 may dispense such health related information to the user computer 108 (Fig. 1, page 2, paragraph [0029]). Further, Rienhoff teaches the claimed "the servicing means being operative to deliver messages between two users" as the information could be directed to individual users via email or web pages viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph [0047]). Further, Rienhoff teaches the claimed "a database for storing user data and study data" as phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph

[0039]). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082).

Further, Rienhoff teaches the claimed "the study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, and at least one dataset associated with at least one of the candidate subjects" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further, Rienhoff and Fagan do not explicitly teach event data. However, Bianco teaches "event data for tracking events associated with medical treatment of candidate subjects" as electronic patient healthcare system 1 and method for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery (Fig.1, page3, 3, paragraph [0078]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Bianco's teachings would have allowed Rienhoff's system to provide an interactive, electronic patient healthcare system to facilitate a full array of education and preparation tools for guiding a patient through a medical event (see Bianco, page 1, paragraph [0010]).

Further, Rienhoff and Bianco do not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed "at least one dataset and wherein the dataset is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected

datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (page 1, paragraph 0005).

Finally, Rienhoff, Fagan and Bianco do not teach explicitly role-based access control. However, Smirniotopoulos teaches the claimed, the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user, access to the system for specified roles (Fig. 2, col. 3, lines 32-49). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Smirniotopoulos' teachings would have allowed Rienhoff's system to provide a system that is robust, interactive, and permits geographically remote practitioners to create, update, and relationally search multimedia medical information (see Smirniotopoulos, col. 1, lines 39-42).

31. As per independent claim 37, Rienhoff teaches a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of

being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph [0006]). Rienhoff teaches the claimed "a computer system operable to service user requests and provide users with information responsive to the user requests" as database is queried to get information (Fig. 10, page 12, paragraph [0135]). Further, Rienhoff teaches the claimed "a database with a flexible database structure that facilitates the study definition process for various studies" as a submitted biological sample may be analyzed for phenotypic and genotypic information and populate the database (Fig. 5, page 7, paragraph [0072]).

Further, Rienhoff teaches the claimed "presentation creation means operable to provide users with dynamic information" as the user can access and retrieve data from a remote database via a computer network such as a LAN or the internet (Fig. 1, page 3, paragraph [0034]). Further, Rienhoff teaches the claimed "application control and navigation means operable to service user requests" as the individual users accessing a web site and get the offered information on health-related issues and a variety of diseases and medical conditions (page 2, paragraph 0025).

Further, Rienhoff teaches the claimed "data access means operable to access information that resides in a system database wherein the database is operable to store user data and study data (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108,

information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082).

Further, Rienhoff teaches the claimed "the study data includes candidate data associated with candidate, subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, and at least one dataset associated with at least one of the candidate subjects" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further, Rienhoff and Fagan do not explicitly teach event data. However, Bianco teaches "event data for tracking events associated with medical treatment of candidate subjects" as electronic patient healthcare system 1 and method for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery (Fig.1, page3, 3, paragraph [0078]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Bianco's teachings would have allowed Rienhoff's system to provide an interactive, electronic patient healthcare system to facilitate a full array of education and preparation tools for guiding a patient through a medical event (see Bianco, page 1, paragraph 0010).

Finally, Rienhoff and Bianco do not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed "at least one dataset and wherein the dataset is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3,

paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph [0005]).

Further, Rienhoff teaches the claimed "the computer system is operable to limit communication of electronic messages between users to those users having a specific role in connection with a specific study" as the information could be directed to individual users via email or web pages viewable to group of users who have registered with the web site (Fig. 1, page 4, paragraph 0047).

Finally, Rienhoff, Fagan and Bianco do not teach explicitly role-based access control. However, Smirniotopoulos teaches the claimed, the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user, access to the system for specified roles (Fig. 2, col. 3, lines 32-49). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Smirniotopoulos' teachings would have allowed Rienhoff's system to provide a system that is robust, interactive, and permits geographically remote

practitioners to create, update, and relationally search multimedia medical information (see Smirniotopoulos, col. 1, lines 39-42).

32. As per dependent claim 38, Rienhoff teaches the claimed "application and data security means operable to limit users access to information in the system database" as a tool for users to build a secure online medical record, providing users with secure, but convenient to use their own medical information and stored in database 105. Additionally, users may give the option to let select others access their medical records (Fig. 1, page 4, paragraph 0046).

33. As per dependent claim 39, Rienhoff teaches the claimed "the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events" as the database and it is inherent that all databases will have tables (Fig. 9, page 12, paragraph 0129).

34. As per dependent claim 40, Rienhoff teaches the claimed "the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events" as the database and it is inherent that all databases will have tables (Fig. 9, page 12, paragraph 0129).

35. As per dependent claim 41, Rienhoff teaches the claimed "the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events" as the database and it is inherent that all databases will have tables (Fig. 9, page 12, paragraph 0129).

36. As per dependent claim 42, Rienhoff teaches the claimed "the database has tables with Gelds associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events" as the database and it is inherent that all databases will have tables (Fig. 9, page 12, paragraph 0129).

37. As per dependent claim 43, Rienhoff teaches the claimed "the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events" as the database and it is inherent that all databases will have tables (Fig. 9, page 12, paragraph 0129).

38. As per dependent claim 44, wherein each of the events relates to an occurrence in time of an interaction with a study subject or patient for which the at least one dataset is collected" as an individual's biological sample can include blood, serum, saliva etc. (page 10, paragraph 0107).

39. As per dependent claim 45, Rienhoff teaches the claimed "an event is an initial visit, a surgery, or a follow up visit or treatment" as the queries could be for entries of surgical procedures (page 6, paragraph [0069]).

40. As per dependent claim 46, Rienhoff teaches the claimed "further comprising tracking the events, wherein each of the events is either scheduled or unscheduled such that, if scheduled, the events are predefined, wherein each of the events has a status associated therewith for tracking progress" the registration is the process of receiving a biological sample such as blood or DNA samples (page 10, paragraph 0108).

41. As per independent claim 47, Rienhoff teaches by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches as a server application has a multi-tier architecture including a first tier of client and a middle tier of object-oriented server application code and a third tier of shared access and data code (Fig. 1, page 3, paragraph 0037). Further, Rienhoff teaches the claimed "a client tier having presentation, presentation logic and user interface portions"

as the client tier (Fig. 1, page 3, paragraph 0037), "a middle tier including application control, business logic and data access portions" as server application tier (Fig. 1, page 3, paragraph 0037), "a data tier including a database and database management portion, wherein the database is configured for storing user data and study data" as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028 and page 3, paragraph 0036), Further, Rienhoff teaches the claimed "a channel for communicating data including a data networks wherein the client tier, middle tier and data tire are linked via the channel and enabling access and interaction for clinical research by geographically disparate users" as multiple computers connected over a network such as a LAN, a WAN or the internet (Fig. 1, page 3, paragraph 0037).

Further, Rienhoff teaches the claimed "the study data includes candidate data associated with candidate, subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, and at least one dataset associated with at least one of the candidate subjects" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further, Rienhoff and Fagan do not teach explicitly event data. However, Bianco teaches "event data for tracking events associated with medical treatment of candidate subjects" as electronic patient healthcare system 1 and method for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery (Fig.1, page3, 3, paragraph [0078]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the

cited references because Bianco's teachings would have allowed Rienhoff's system to provide an interactive, electronic patient healthcare system to facilitate a full array of education and preparation tools for guiding a patient through a medical event (see Bianco, page 1, paragraph [0010]).

Finally, Rienhoff and Bianco do not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed "at least one dataset and wherein the dataset is defined using metadata" as the data being displayed in the window is the metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph [0035]). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph [0005]).

Finally, Rienhoff, Fagan and Bianco do not teach explicitly role-based access control. However, Smirniotopoulos teaches the claimed, the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user, access to the system for specified roles (Fig. 2, col. 3, lines 32-49). Thus, it would have been obvious

to one of ordinary skill in the data processing art to combine teaching of the cited references because Smirniotopoulos' teachings would have allowed Rienhoff's system to provide a system that is robust, interactive, and permits geographically remote practitioners to create, update, and relationally search multimedia medical information (see Smirniotopoulos, col. 1, lines 39-42).

42. As per independent claim 48, Rienhoff teaches by disclosing a method and system for populating a database by gathering information from many individuals including family history, lifestyle, clinical and medical history, therapies and phenotype that is capable of being associated with biological sample (e.g., DNA information, etc.) from that individual. Such information can be aggregated and correlations uncovered to provide the basis for product development such as diagnostics, therapeutic selection, behavioral modification, drug discovery, etc (page 1, paragraph 0006). Rienhoff teaches the claimed "defining roles for a clinical study and assigning respective ones of the roles to users of the system for clinical research data management" as a phase II clinical study involves a large patient population (page 12, paragraph 0141). Further, Rienhoff teaches the claimed "managing role-based authentication and authorization, wherein a role has capabilities commensurate therewith" as a person can communicate with the user via telephone, email, internet (page 9, paragraph 0101).

Further, Rienhoff and Bianco do not explicitly teach defining a dataset using metadata. However, Fagan teaches the claimed "defining one or more datasets for the clinical study using metadata" as the data being displayed in the window is the

metadata that describes the protocol and datasets is used to merge the selected datasets and to display the individual variables (see Fagan, Fig. 9-10, page 3, paragraph 0035). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Fagan's teachings would have allowed Further, Rienhoff's system to create a dataset using metadata to include provisions for reengineering the data access and analysis (see Fagan, page 1, paragraph 0005).

Further, Rienhoff teaches the claimed "defining a schedule of events for the clinical study, wherein an event has a status associated therewith" as the online event (page 4, paragraph 0044). Further, Rienhoff teaches the claimed "storing the datasets in a database within the system for clinical research data management, the database being configured for maintaining clinical study data including user information, roles, capabilities" as the system 100 includes a server system 102 coupled with a databases 104 and 105 (Fig. 1, page 2, paragraph 0028). Phenotypic data may be stored in a database 105 and the server system may invite user to submit biological sample to store on database (Fig. 1, page 2, paragraph 0039). In step 614, the user information may be entered into the registration from using the client device 108, information consists of name, address, phone number, email address, etc (Fig. 1, 6, page 7, paragraph 0082). Further, Rienhoff teaches the claimed "imposing role-based restrictions on user access to the clinical study data and on communications between users" as user to restrict others accessing data (page 4, paragraph 0046).

Further, Rienhoff teaches the claimed "candidate data associated with candidate, subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, and at least one dataset associated with at least one of the candidate subjects" as database is queried to get information (Fig. 10, page 12, paragraph [0135]).

Further Rienhoff teaches the claimed "maintaining the status of events by tracking their occurrence and, thereby, monitoring progress of the clinical study" as suggestions include a course of treatment (page 12, paragraph 0137).

Finally, Rienhoff, Fagan and Bianco do not teach explicitly role-based access control. However, Smirniotopoulos teaches the claimed, imposing role based restrictions on the user access to the clinical study data and on communications between users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user, access to the system for specified roles (Fig. 2, col. 3, lines 32-49). Thus, it would have been obvious to one of ordinary skill in the data processing art to combine teaching of the cited references because Smirniotopoulos' teachings would have allowed Rienhoff's system to provide a system that is robust, interactive, and permits geographically remote practitioners to create, update, and relationally search multimedia medical information (see Smirniotopoulos, col. 1, lines 39-42).

43. As per dependent claim 49, Rienhoff teaches the claimed "imposing the restrictions on access includes maintaining an audit trail that records users' access information" as to audit and maintain their own records (page 4, paragraph 0046).

44. As per dependent claim 50, Rienhoff teaches the claimed "the access information includes user's identity, time of access, type of access and level of access" as the users may be given strict control, who can access and which information can be accessed (page 4, paragraph 0041).

45. As per dependent claim 51, Rienhoff teaches the claimed "a dataset includes data items, and wherein the level of access is a dataset level, data item level, or both" as what form of information provided to others (page 4, paragraph 0041).

46. As per dependent claim 52, Rienhoff teaches the claimed "the roles include data monitor, enroller, data editor, study administrator and system administrator" as users may be given the option to let selected others (e.g., their physicians) access their medical records (page 4, paragraph 0046).

47. As per dependent claim 53, Rienhoff teaches the claimed "each capability maps to a functional portion of the system for clinical research data management" as the medical records are also linked to family history (page 4, paragraph 0046).

48. As per dependent claim 54, Rienhoff teaches the claimed "the functional portions include one or more of backup database, create study, deploy study, close study, open enrollment, close enrollment, define business rules, enroll subject, disenroll subject, view enrollee, export enrollee list, create profile, disable profile, assign role, disable role, export collaborator list, delete user, approve dataset, retract approval, view data, edit dataset, add dataset, suspend edit capabilities, reinstate edit capabilities, export dataset" as the enrollment procedures (page 4, paragraph 0047).

49. As per dependent claim 55, Rienhoff teaches the claimed "deploying for the clinical study one or more functional elements of the system for clinical research data management including login, candidate registration, specimen registration, study administration, data monitoring, data administration, data editing, and communication" as user authority (page 4, paragraph 0048).

Response to Arguments

50. Applicant's arguments filed 7/18/2006 have been fully considered but they are moot in view of the new ground of rejection. Rienhoff, Fagan and Bianco references are combined with the newly found Smirniotopoulos reference, teaches each and every limitation of all claims as discussed above.

Conclusion

51. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sathyanarayan Pannala whose telephone number is (571) 272-4115. The examiner can normally be reached on 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Rones can be reached on (571) 272-4085. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRP
Sathyanarayan Pannala
Examiner

srp
October 14, 2006

MOHAMMAD ALI
PRIMARY EXAMINER